REMARKS

Reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the amendments, remarks, and enclosures herewith, which place the application in condition for allowance.

I. Status Of Claims And Formal Matters

The specification has been amended to clarify that the Schering-Plough vaccine of Table 6 is the Coccivac vaccine of Example 2. No new matter has been added by this amendment.

Claims 1 to 14 are pending in this application. Claim 1 has been canceled, without prejudice. Claims 2-7, 9 and 12 have been amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. No new matter has been added.

Support for the recitation of a mixture of sporulated oocysts isolated from precocious strains of *E. acervulina, E. maxima, E. mitis* and *E. tenella*, wherein for every 10 sporocysts of *E. acervulina*, there are about 1 to 2 sporocysts of *E. maxima*, about 10 sporocysts of *E. mitis* and about 2 to 10 sporocysts of *E. tenella* may be found at page 4, lines 13 to 20 of the specification as originally filed.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. The Claim Objections Are Overcome

Claims 7 and 9 are objected to because of the following informalities: there is an inappropriate spacing in the words "o f" and "c omposition" in the claims. In response, Applicants respectfully point out that the appropriate corrections have been made, thereby obviating the objection.

Reconsideration and withdrawal of the objection to the claims is requested.

III. The Rejections Under 35 U.S.C. §112, Second Paragraph, Are Overcome

Claims 4, 5, 8, 9, 12, 13 and 14 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner alleges that the recitation of the ratio of *E. acervulina:E. maximia:E. mitis:E. tenella* is about 10:1 to 2:10:2 to 5 in claim 4 is vague and confusing. In response, claim 4 has been clarified to recite an immunogenic or vaccine composition comprising a mixture of sporulated oocysts isolated from precocious strains of *E. acervulina, E. maxima, E. mitis* and *E. tenella*, wherein for every 10 sporocysts of *E. acervulina*, there are about 1 to 2 sporocysts of *E. maxima*, about 10 sporocysts of *E. mitis* and about 2 to 10 sporocysts of *E. tenelli,* thereby obviating the rejection.

The Examiner alleges that the recited ratio of 5:1:5:1 in claims 5 and 12 are vague and confusing. In response, claims 5 and 12 have been clarified to recite compositions wherein for every 10 sporocysts of *E. acervulina*, there are about 1 sporocysts of *E. maxima*, about 10 sporocysts of *E. mitis* and about 2 sporocysts of *E. tenella*, thereby obviating the rejection.

Reconsideration and withdrawal of the Section 112 rejections are earnestly requested.

IV. The Rejections Under 35 U.S.C. §112, First Paragraph, Are Overcome

Claims 1-14 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for "vaccine compositions for protection against *E. tenella, E. maxima, E. acervulina* and *E. mitis* consisting essentially of a mixture of sporulated oocysts isolated from precocious strains of *E. tenella, E. maxima, E. acervulina* and *E. mitis*" and methods for inducing a protective immune response against *E. tenella, E. maxima, E. acervulina* and *E. mitis* through the administration of said vaccine, does not allegedly reasonably provide enablement for vaccines or protective methods which cross protect against all species of Eimeria as instantly claimed.

Although Applicants do not agree with the Examiner, in the interest of expediting prosecution, claims 2 and 4 have been clarified to recite an immunogenic or vaccine composition for protection against *E. acervulina, E. maxima, E. mitis* and *E. tenella* to obviate the rejection.

Reconsideration and withdrawal of the Section 112 rejections are earnestly requested.

V. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 1, 6 and 7 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by

Schmatz et al. (WO 94/16725). Claims 1, 6 and 7 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Evans et al. (WO 96/40234) which corresponds to U.S. Patent No. 6,495,146 B1. Claims 1, 6 and 7 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by McDonald et al. (U.S. Patent No. 5,055,292).

Applicants respectfully point out that claim 1 has been canceled, thereby rendering the rejection moot.

Reconsideration and withdrawal of the Section 102 rejections are earnestly requested.

VI. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 2-5 and 8-14 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any one of Schmatz et al. (WO 94/16725), Evans et al. (WO 96/40234) or McDonald et al. (U.S. Patent No. 5,055,292).

The Examiner is respectfully directed to the case law, namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." For the §103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed.Cir. 1988).

As indicated in the background of the instant invention, there are problems with existing coccidiosis vaccines, such as reduced efficacy, cross-infection with other parasites (e.g., *Clostridium sordelli*) and poor bird performance. Therefore, there exists a need for efficacious coccidiosis vaccines with reduced or non-existent cross-infection that do not adversely affect bird performance.

As indicated on page 6, lines 13-22 of the specification, in consideration of the prevalence and pathogenicity of various *Eimeria* species, a successful attenuated coccidiosis vaccine should contain the least number of *Eimeria* strains sufficient to elicit an immune response or induce an immunological or protective response that is non-pathogenic to the recipient of the vaccine. The present relation relates to a combination of oocysts from four

specific precocious strains of *Eimeria*, i.e., *E. acervulina, E. maxima, E. mitis* and *E. tenella* that results in an efficacious and non-pathogenic vaccine. The addition of other *Eimeria* strains, such as *E. brunetti, E. necatrix* and *E. praecox* may be disadvantageous with respect to efficacy, cross-infection or pathogenicity of the vaccine. Since *E. brunetti, E. necatrix* and *E. praecox* are not necessary for the efficacy of the coccidiosis vaccine disclosed herein, it would be advantageous to exclude these strains from the vaccine of the present invention.

Applicants respectfully direct the Examiner's attention to Example 2 of the specification. Birds vaccinated with Coccivac vaccine (which contains *E. mivati* instead of *E. mitis*) became infected with *Clostridium sordelli* whereas the birds vaccinated with the presently claimed vaccine were not infected. Accordingly, the presently claimed invention is advantageous because it excludes *Eimeria* strains that are not necessary for the efficacy of the cocciodis vaccine, which results in a non-pathogenic vaccine.

Schmatz, Evans or McDonald, alone or in combination, do not teach or suggest the exclusion of any of the *Eimeria* strains not necessary for the efficacy of the presently claimed invention. Instead, Schmatz, Evans or McDonald broadly illustrate that a mixture of two to seven strains (Schmatz), two or more strains (Evans) or at least 3 strains (McDonald) of *Eimeria* can be used. Thus, Schmatz, Evans and McDonald relate to a large number of possible combinations of *Eimeria* strains and do not teach or suggest the exclusion of any of the *Eimeria* strains not necessary for the efficacy of the presently claimed invention.

Schmatz, Evans or McDonald do not teach or suggest any of the dosages or ratios of oocysts of the present invention. Contrary to the Examiner's contention, variation of the ratio/range of oocysts to a range which is optimal is not routine experimentation, especially since the general conditions of the claimed invention (e.g., presence of *E. acervulina, E. maxima, E. mitis* and *E. tenella* and exclusion of other *Eimeria* strains) are absent in Schmatz, Evans and McDonald.

As indicated above, the present invention fulfills a need in the art for efficacious coccidiosis vaccines with reduced or non-existent cross-infection that do not adversely affect bird performance. The instant invention is based, in part, on an attenuated coccidiosis vaccine that is efficacious in the face of virulent challenge, reduced cross-infection with *Clostridium spp.* and has better bird performance as defined by feed conversion rates when compared to other coccidiosis vaccines. Thus, the presently claimed vaccine is superior to other coccidiosis

vaccines in that it is efficacious in the face of virulent challenge, results in reduced cross-infection with *Clostridium spp.* and has better bird performance as defined by feed conversion rates when compared to other coccidiosis vaccines. Accordingly, the presently claimed invention fulfills a need in the art for an efficacious coccidiosis vaccine with reduced or non-existent cross-infection that does not adversely affect bird performance.

Reconsideration and withdrawal of the Section 103 rejections are earnestly requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested; and, the Office Action is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

MERIAL LIMITED
FROMMER LAWRENCE & HAUG LLP

By: _____

Judy Jarecki-Black, Ph.D., J.D.
Reg. No. 44,170
Telephone: (678) 638-3805
Facsimile: (678) 638-3350
Thomas J. Kowalski
Reg. No. 32,147
Telephone: (212) 588-0800
Facsimile: (212) 588-0500